K042646

OCT 19 2004

510(k) Summary for the Siemens DynaCT

27 September, 2004

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Contact Person:

Mrs. Ana Ladino
Regulatory Submissions
Phone: (610) 448-1785 Fax: (610) 448 1787

2. Device Name and Classification:

Trade Name:	DynaCT
Classification Name:	Accessory to Angiographic X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1600
Device Class:	Class II
Product Code:	90JAA

3. Substantial Equivalence:

The DynaCT is designed for three-dimensional evaluation of data acquired with a standard angiographic C-arm device. The package is substantially equivalent to the following devices:

Device Name	FDA Clearance Number	FDA Clearance Date
Siemens In Space 3D Software Option	K011447	08/03/01
Siemens Siremobil Iso C 3D Imaging Option	K003266	10/18/00

In summary, Siemens is of the opinion that DynaCT does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate devices

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4. Device Description:

The DynaCT is an x-ray imaging software option, which allows the reconstruction of two-dimensional images acquired with a standard angiographic C-arm device into a three-dimensional image format. DynaCT provides extended visualization capability. An increased number of acquired and post processed images results in an improved visualization of soft tissues. This improved visualization is comparable to CT images.

5. Intended Use of the Device:

DynaCT is an x-ray imaging software option, which allows the reconstruction of two-dimensional images acquired with a standard angiographic C-arm device into a three-dimensional image format.

DynaCT is intended for imaging both hard and soft tissues as well as other internal body structures for diagnosis, surgical planning, interventional procedures and treatment follow-up.

6. Summary of Technological Characteristics of the Devices Compared to the Predicate:

The Siemens DynaCT software option of the In Space 3D software package and the Siremobile 3D software allows construction of a three-dimensional model from two dimensional images acquired during rotational angiography.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 19 2004

Mrs. Ana Ladino
Technical Specialist
Siemens Medical Systems, Inc.
51 Valley Stream Parkway
MALVERN PA 19355

Re: K042646
Trade/Device Name: DynaCT
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: 90 IZI
Dated: September 23, 2004
Received: September 28, 2004

Dear Mrs. Ladino:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042646
Device Name: DynaCT

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DynaCT is intended for imaging both hard and soft tissues as well as other internal body structures for diagnosis, surgical planning, interventional procedures and treatment follow-up.

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042646